

Applicants describe the synthetic production of the recited peptides in the specification at, for example, page 15, lines 18-24. One of skill in the art could have used the peptides so produced to raise antibodies, make monoclonal antibodies, and isolate antibodies from serum with only routine experimentation. This is the only guidance one of skill in the art would need since the techniques of expressing peptides from DNA were well known at the time of filing. An applicant preferably omits descriptions of well known techniques from a patent specification. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534, 3 U.S.P.Q.2d 1737, 1743 (Fed. Cir. 1987), citing Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986) *cert. denied*, 107 S. Ct. 1606 (1987). The present specification conforms to that preference.

As noted, the specification states that the claimed peptides can be expressed by known recombinant DNA technologies. Such a statement must be taken as placing the claims in compliance with 35 U.S.C. § 112, first paragraph, unless one of skill in the art would doubt the objective truth of the statements. In re Brana, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1995); citing In re Marzocchi, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

The Examiner asserts that undue experimentation would have been required to express the recited peptides. However, there

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is no evidence that shows that one of ordinary skill in the art would doubt applicants' statements in the specification.

For example, the Examiner states that :

... at the time the invention was made, there remained the unpredictability associated with obtaining a proper protein from a single ORF. Very little was known about the gene products encoded by the HIV ORFs at the time the invention was made. In fact, there was no indication that HIV gene products could be effectively expressed recombinantly. Paper No. 15 at page 3.

The Examiner appears to recognize the novelty and nonobviousness of the claimed invention. The inventors had successfully sequenced the HIV-1 genome and characterized it with respect to other retroviruses. Their analysis, disclosed in the specification, also led to the knowledge of where peptides and proteins were encoded in the HIV-1 genome. Thus, they enabled the production, by recombinant methods or otherwise, of the recited peptides. No reasons existed and no contradictory results indicated that one of skill in the art could not have made and used the claimed invention herein at the time the invention was made from the recombinantly expressed peptides.

In fact, Applicants respectfully note that there is no evidence cited by the Examiner that one of ordinary skill in the art could rely on to support the conclusion that the claimed invention is not enabled by the specification. If the evidence exists in the Examiner's personal knowledge, it should be presented in the form of an Examiner's Affidavit under 37 C.F.R. 1.107(b) so that applicants can properly respond to it. In

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light of the fact the Examiner has provided no support for the conclusion that the ORFs of HIV-1 could not have been expressed, one of skill in the art would have no reason to doubt the specification. Therefore, a *prima facie* case of lack of enablement has not been made.

Furthermore, applicants respectfully note that the reasoning in the rejection would require an applicant to "reinvent the wheel" every time a new source of DNA is characterized or isolated. One of skill in the art would not have hesitated to use the known recombinant techniques to express any DNA newly isolated. And there is no undue experimentation in using those techniques.

Applicants also respectfully point out that while this art is sometimes referred to as "unpredictable," applicants are not required to make it predictable. Thus, "predictability" is not a factor in the analysis of 35 U.S.C. § 112, first paragraph, but the extent of experimentation to practice the invention is.

Here, one of skill in the art was familiar with probably hundreds of cases where a DNA in the form of an ORF was used to produce a peptide or protein. Applicants previously submitted Gray et al., Proc. Natl. Acad. Sci. U.S.A., 79; 6598 (1982), which shows that methods and vectors for the expression of ORFs were known before the claimed invention was made (see Exhibit 2 in the Amendment filed December 20, 1994). The Examiner had asserted that the *tat* gene was a "split ORF" and, thus, apparently, would have rendered useless the thousands of

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successful examples available. Paper No. 12 at page 3. However, the present claims nowhere recite a tat gene, so this reasoning does not apply to the present claims. Thus, there is no reason one of skill in the art would not consider the claimed invention enabled in light of the clear teachings of at least Gray et al.

In Paper No. 15, at page 3, the Examiner asserts that the claimed invention is not enabled "as the disclosure provides no teaching of the intricacies involved with HIV peptide expression." But what are those intricacies? The only possible reason presented to doubt applicants' statements in the specification were the comments related to the "split ORF." Since these no longer apply, no reason exists in the record.

At page 4 of Paper No. 15, the Examiner further asserts that "even if one were able to make the gene product from the desired ORF, one could not predict that these proteins would elicit antibodies which are detectable in serum." As noted above, predictability is not required under 35 U.S.C. § 112, first paragraph. Furthermore, the Examiner has pointed to no reason why one of skill in the art would believe that antibodies could not have been raised or isolated with the recited peptides. Without such evidence, there can be no *prima facie* case of lack of enablement.

For these reasons, the objection and rejection are in error and should be withdrawn.

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Claims 11, 13 and 15 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kalyanaraman or Schupbach et al. as evidenced by Arya et al., Wong-Staal, and Cohen et al. This rejection is respectfully traversed.

Initially, applicants note the dates of the cited documents: the date of the Schupbach document is May 4, 1984; Kalyanaraman states a date of July 20, 1984. However, the date of each of Wong-Staal, Cohen, and Arya is later than that of applicants' foreign priority document, October 18, 1984. Therefore, none of Wong-Staal, Cohen, or Arya is "prior art" to this application.

The Examiner notes at page 5 of Paper No. 15, that "the language 'isolated' [in the claims] has been interpreted to read on antibodies or antisera which is separated from the body." Applicants respectfully submit that this cannot be a reasonable interpretation of the claim language since it would mean that "isolated" is equivalent to "separated from the body." That is not how one of ordinary skill in the art would define "isolated." "Isolate" is defined in the pertinent parts of the American Heritage College Dictionary, third edition (1993), as:

... 3. *Chem.* To separate (a substance) out of a combined mixture.... 5. *Microbiol.* To separate (a pure strain) from a mixed bacterial or fungal culture....

The Examiner's interpretation does not seem to take into account the "separate out of a combined mixture" aspect of the word which one ordinarily understands. One of skill in the art would

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not understand "an isolated antibody" to mean the same as a drop of serum, even if the drop is from an AIDS patient or pre-AIDS patient as used in Schupbach or Kalyanaraman. Since claims must be read as one of skill in the art would reasonably understand them, applicants respectfully submit that the Examiner's interpretation is in error. Therefore, the Examiner's conclusion and the reasons for this rejection are also in error and should be withdrawn.

The rejection is allegedly buttressed by the Arya, Wong-Staal, and Cohen documents. As these documents are not statutory "prior art," they are apparently used to show that Schupbach and Kalyanaraman inherently disclose the claimed invention.

However, in order to show an inherently anticipatory disclosure, each and every element of the claimed invention must "flow undeniably from the express disclosure" of either Schupbach or Kalyanaraman. See Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988). Furthermore, either Schupbach or Kalyanaraman must be enabling for the claimed invention in order to properly anticipate under 35 U.S.C. § 102(b). In re Donohue, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). Since neither of these appropriate legal standards have been met, there is no *prima facie* showing of anticipation.

Nowhere within the four corners of Schupbach or Kalyanaraman is there any mention of the recited peptides from the ORFs of HIV-1. This is an elementary aspect of the claimed

invention. Without disclosing these peptides, neither Schupbach nor Kalyanaraman can possibly disclose each and every element of the claimed invention.

Furthermore, the later published documents do not show why the claimed invention would have undeniably flowed from the disclosure in Schupbach or Kalyanaraman. The only way the later published documents can be relevant is when the improper interpretation of the "an isolated antibody" language is used. Since applicants have shown above the errors in this interpretation, the later published documents do not show that Schupbach or Kalyanaraman disclose each and every element of the claimed invention.

In addition, the Examiner concludes in Paper No. 15, at page 6, by asserting that:

"...the fact that the references [Schupbach and Kalyanaraman] were not looking for antibodies to the ORFs does not detract from the fact that these antibodies were actually present in the serum of the HIV infected patients...."

However, this assertion is in error and does not set forth a case where an alleged teaching "flows undeniably" from the documents, as required under the law of anticipation. See Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988).

In order for any conclusion about the antibody content of the serum tested in Schupbach or Kalyanaraman to "flow undeniably" from a comparison to the later published documents, there must be some evidence that the serum "actually" used

contains the same antibodies as the serum described in any of Arya, Wong-Staal, or Cohen (the later published documents). For that to be the case, one would have to know either that the same serum sample was used or that every HIV-infected patient has the exact same antibodies in their serum through the course of infection. Since the Examiner has pointed to no evidence for such conclusions from the documents cited, and none in fact exists, it cannot "flow undeniably" from Schupbach or Kalyanaraman that the serum used contains the same antibodies as in the later published documents.

Finally, neither Schupbach nor Kalyanaraman enable the claimed invention since neither mention the recited peptides or even the ORFs from HIV-1. Without the DNA sequence of HIV-1 encoding the recited peptides, Schupbach or Kalyanaraman cannot possibly enable one to make the claimed invention. The later published documents cannot be used to show that Schupbach or Kalyanaraman do enable the claimed invention because any sequence data contained in them was not known and could not have been inherently disclosed by Schupbach or Kalyanaraman. Therefore, neither of these documents can properly be used to show anticipation of the claimed invention.

For these reasons, this rejection is in error and should be withdrawn.

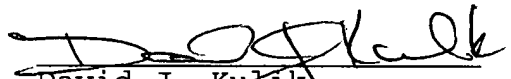
Reconsideration and reexamination of this application, and allowance of the pending claims at the Examiner's convenience, are courteously requested.

If there are any fees due in connection with the filing of this Response, please charge such fees to our Deposit Account No. 06-0916. If a fee is required for an Extension of Time under 37 C.F.R. § 1.136 not accounted for above, such an Extension is requested and fee should also be charged to our Deposit Account.

Respectfully submitted,

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